REMARKS

Reconsideration of the present application in view of the above amendments and following remarks is respectfully requested. Claims 12, 15-17, 19, 21, 23, 27, 30-32, 34, 36-38, 40, 42, 44, and 54-69 were pending. As set forth above, Applicant has hereby cancelled claims 12, 15-17, 19, 21, 23, 27, 30-32, 34, 36-38, 40, 42, 44, and 54-69 without prejudice to the filing of any divisional, continuation or continuation-in-part application, and hereby submits new claims 70-103. Support for the new claims may be found in the application as originally filed. For instance, support may be found in the specification as originally filed, in part, at page 6, line 4 through page 7, line 31, Examples 3, 5, and 7 (*see, e.g.*, claims 80 and 99); at page 9, lines 1-14 (*see, e.g.*, claims 81 and 100); at page 16, lines 24-26 (*see, e.g.*, claims 83 and 102); and at page 17, lines 11-13 (*see, e.g.*, claims 84 and 103). Additionally, the new claims essentially parallel previously pending (*e.g.*, new claims 70 and 85 are similar to previously pending claims 12 and 27, respectively). Furthermore, Applicant has hereby amended the specification to provide a definition of the pQE30 expression vector, which was an art recognized definition of pQE30 at the time of the filing the instant application (*see* MPEP §2163,07(I)); that is, pQE30 is a 6xHis-tag expression vector (*see* enclosed Qiagen documents entitled "pQE-30, pQE-31, and pQE-32 Vectors"; and "QIAexpress®: The Complete System for 6xHis Technology," at pages 3-6). Moreover, the description of the pQE30 expression vector merely recites the inherent function of the vector, which is to add a 6xHis-tag to a polypeptide being expressed from this vector, and, therefore, the description of pQE30 does not introduce new matter (*see* MPEP §2163.07(a)). Consequently, support for new claims 82 and 101 may be found in the application as originally filed, in part, at page 9, lines 13-14; at page 16, lines 24-26; and at page 17, lines 9-10. Therefore, claims 70 - 103 are currently pending.

Applicant wishes to thank Examiner Devi for her helpful comments and suggestions during a telephone interview with the undersigned on October 10, 2003.

REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

In the Office Action dated July 15, 2003, claims 12, 15-17, 19, 21, 23, 27, 30-32, 34, 36-38, 40, 42, 44, and 54-69 were rejected under 35 U.S.C. §112, second paragraph, as

indefinite. Specifically, it is first alleged that the phrase "at least one immunogenic polypeptide" of claims 12 and 27 is unclear because these polypeptides may come from an amino-terminal portion or a non-amino-terminal portion of a Group A streptococcal M protein. Second, it is alleged that the source of "immunogenic polypeptides" as recited in claims 16, 37, and 56 is unclear. Finally, it is alleged that it is unclear what "each M protein portion" refers to in claims 55, 57, 60 and 62, and that this phrase impermissibly broadens the base claim.

Applicant respectfully traverses these grounds of rejection and submits that the source of the immunogenic polypeptides of the immunogenic portion as being from the amino-terminal portion of a streptococcal protein, as described in the specification and recited in the claims, is clear to a person having ordinary skill in the art. Nevertheless, however, merely to expedite prosecution of the instant application, the previously pending claims have been hereby cancelled and new claims have been submitted herewith to more clearly define the subject matter encompassed by the Applicant's invention. Accordingly, the instant invention is directed, in part, to a recombinant fusion polypeptide, comprising a multivalent immunogenic portion fused to an immunogenic polypeptide carboxy-terminal to the multivalent immunogenic portion, which protects the immunogenicity of the multivalent immunogenic portion, wherein the multivalent immunogenic portion comprises at least two immunogenic amino-terminal polypeptides of Group A streptococcal M protein from at least two different streptococcal serotypes, and wherein the immunogenic polypeptide carboxy-terminal to the multivalent immunogenic portion is a reiteration of the immunogenic amino-terminal polypeptide from the amino terminus of the multivalent immunogenic portion.

Applicant submits that the currently pending claims meet the requirements for definiteness under 35 U.S.C. § 112, second paragraph. Therefore, Applicant respectfully requests that this rejection be withdrawn.

REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (NEW MATTER)

In the Office Action, claims 12, 27, and 64-69 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter not supported in the specification. In particular, it is alleged that (1) the phrase "reiteration of at least one immunogenic polypeptide," of claims 12 and 27 lacks descriptive support in the specification; (2) the absence

of the "10 amino acids in length" limitation for immunogenic polypeptides constitutes new matter; and (3) there is no support for a "marker amino acid sequence," "amino acids encoded by a restriction enzyme site," or "a marker or inconsequential amino acid sequence capable of binding nickel resin," as recited in claims 64-69.

Applicant respectfully traverses these grounds of rejection and submits that the claim recitations are described and supported in the specification as originally filed. With regard to the reiterated immunogenic polypeptide, the specification discloses that the carboxy-terminal of the claimed recombinant fusion polypeptide may include a selective portion or an inconsequential non-immunogenic polypeptide or a reiterated immunogenic polypeptide. Thus, the open language used to describe the different potential carboxy-terminal additions indicates that more than one addition may be fused to the recombinant fusion polypeptide of the instant invention. Furthermore, Applicant respectfully submits that the mere fact that exemplified embodiments in the specification are more limited than those recited in the claims does not provide sufficient reason for the Examiner to hold the claims as lacking written support or enablement. Applicant is not required to specifically exemplify all embodiments of the invention that are encompassed by the claims. The requirements of 35 U.S.C. §112, first paragraph can be fulfilled by the use of *illustrative* examples or by broad terminology. *In re Anderson*, 176 USPQ 331 (CCPA 1973). With regard to deleting the recitation of 10 amino acids in the claims, Applicant respectfully disagrees with the allegation that new matter is introduced in claims lacking this recitation because the instant specification describes how to identify M protein "peptides" suitable for use as an "immunogenic polypeptide" according to the instant invention (*see, e.g.*, specification at page 6, line 4 through page 7, line 28).

Nevertheless, however, merely to expedite prosecution of the instant application and without acquiescing to the instant rejections, Applicant has provided a new claim that is directed to, in part, a recombinant fusion polypeptide, comprising a multivalent immunogenic portion fused to an immunogenic polypeptide carboxy-terminal to the multivalent immunogenic portion, wherein the multivalent immunogenic portion comprises at least two immunogenic amino-terminal polypeptides of Group A streptococcal M protein, wherein each of the immunogenic amino-terminal polypeptides is at least 10 amino acids in length, and wherein the immunogenic polypeptide carboxy-terminal to the multivalent immunogenic portion is a

reiteration of the immunogenic amino-terminal polypeptide from the amino terminus of the multivalent immunogenic portion. Thus, the first two new matter rejections as set forth above have been rendered moot.

With regard to the last new matter rejection and as previously made of record, Applicant submits that the specification describes that expression vectors of the instant invention may include markers, such as selectable markers or implicitly markers used to, for example, purify proteins (*e.g.*, use of the pQE30 6xHis-tag expression vector; *see* specification, at page 9, line 1-14). For example, a person having ordinary skill in the art would understand that Example 1 describes an exemplary embodiment of a nucleic acid sequence that encodes a recombinant fusion polypeptide of the instant invention, which was cloned into the pQE30 6xHis-tag expression vector to generate a nucleic acid sequence encoding a recombinant fusion polypeptide further comprising a 6xHis-tag marker. The pQE30 construct was sequenced (*see* specification at page 17, lines 9-10) to verify the nucleotides encoding the recombinant fusion polypeptide were correct, and was impliedly used to express a recombinant fusion polypeptide comprising a 6xHis-tag marker for purification over a Ni-NTA column (*see* specification, at page 16, lines 24-26; see also enclosed article from Qiagen News Issue 4, 1997, entitled "Ni-NTA resins – your key to efficient purification of 6xHis-tagged proteins"). Furthermore, in this exemplary embodiment, the immunogenic polypeptides of the immunogenic portion were joined by two amino acids specified by a restriction endonuclease site as described in the specification (*see* specification at page 17, lines 11-13). Thus, the specification clearly provides support for a "marker" as recited in current claims 81 and 100, for a marker that is "a 6xHis tag" as recited in current claims 82 and 101, for "amino acids specified by a restriction enzyme site" as recited in current claims 84 and 103, and for a marker "capable of binding nickel resin" as recited in current claims 83 and 102.

Accordingly, Applicant respectfully submits that the claimed subject matter is adequately supported by the specification as required under 35 U.S.C. § 112, first paragraph and, therefore, requests that this rejection be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 102(b)

In the Office Action, claims 12, 15, 17, 19, 21, 23, 27, 30, 31, 36, 38, 40, 42, 44, 54, 58, 59, and 63-69 were rejected under 35 U.S.C. §102(b) as anticipated by WO 94/06421 (Dale *et al.*).

Applicant respectfully traverses this ground of rejection. Applicant respectfully submits that the instant rejection was based on a claim interpretation due to the indefiniteness rejections described above. As set forth above, the indefiniteness rejections have either been overcome or rendered moot. Accordingly, the instant rejection has also been rendered moot.

Therefore, Applicant respectfully submits that the present invention satisfies the requirements of 35 U.S.C. § 102(b), and requests that this rejection be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 103(a)

In the Office Action, claims 27, 32, and 34 were rejected under 35 U.S.C. §103(a) as obvious over WO 94/06421 (Dale *et al.*) in combination with U.S. Patent No. 5,334,379 (Pillai *et al.*).

Applicant respectfully traverses this ground of rejection. Applicant respectfully submits that the instant rejection was based on a claim interpretation due to the indefiniteness rejections described above. As set forth above, the indefiniteness rejections have either been overcome or rendered moot. Accordingly, the instant rejection has also been rendered moot.

Applicant respectfully submits that a *prima facie* case of obviousness has not been established under 35 U.S.C. § 103(a) and, therefore, requests that this rejection be withdrawn.

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the pending claims (70-103) in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. The Examiner is urged to contact the undersigned attorney if there are any questions prior to allowance of this matter.

Respectfully submitted,

James B. Dale

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Enclosures:

Qiagen document entitled "pQE-30, pQE-31, and pQE-32 Vectors"
Qiagen document entitled "QIAexpress®: The Complete System for 6xHis Technology"
Qiagen News Issue 4, 1997, "Ni-NTA resins – your key to efficient purification of 6xHis-tagged proteins"

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